Management System: Quality Assurance and Oversight

Subject Area: Quality Records

Management System Owner: John Sattler
Point of Contact: Ken Armstrong

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1.0 Introduction

This Subject Area describes how the EMCBC organization and management meets the Quality Assurance (QA) Records requirements of EM-QA-001 Criterion 4 – Management/Documents and Records. Control of Non-Quality Assurance records is defined in the Management System Description for Records Management.

Criterion 4 – Management/Documents and Records
QA Records are identified as a subset of government records that have unique control and storage requirements based on the nature of the record and the requirements in NQA-1. Based on EM-QA-001 Rev 1:

The requirements included in this document for QA records are implemented in addition to the Federal requirements issued by the National Archives and Records Administration (NARA). The QAP provides additional requirements but does not alleviate any requirements for Federal records. By incorporating the NQA-1 requirements into the Federal records lifecycle, compliance with both NARA and NQA-1 can be achieved. The following shows how the NQA-1 requirements fit into the Federal records lifecycle:

Creation / Receipt:
 Record Identification: Includes identifying QA records within implementing procedures prior to the start-up of work.

Maintenance / Use:
 Retention: Length of time that records must be kept.
- Federal records (including QA records) are required to be scheduled by content/subject within a specific record series. The record series are found in the NARA-approved DOE Records Disposition Schedules, which provide mandatory instructions for the disposition of Federal records.

 Classification: An additional form of QA record identification for filing purposes.
- QA records are further classified as *lifetime* or *non-permanent* Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. Therefore, lifetime QA records are those associated with *items*.

 Non-permanent records are those required to show evidence that an activity was performed in accordance with applicable requirements, but the records do not need to be retained for the life of the item. Therefore, non-permanent QA records are those associated with *activities*.

 File Arrangement: Arrangement of records by subject (activity/item), chronology, etc., to ensure traceability.

 Authentication: Record that is stamped, initialed, or signed and dated for authentication.

 Receipt Control: Form of validating receipt of records in a centralized location.

 Active Record Storage: QA records are to be stored in 2-hour fire proof cabinets, vault storage or dual storage while in active status.

- QA records are maintained in active storage that protects the records from loss or damage by employing filing equipment suitable for the level of protection defined in NQA-1 until the item is no longer being used or it is retired from service (lifetime) or until the records are no longer required to support the work activity (non-permanent).
- When the QA records become inactive, the responsible personnel transfer the QA records to inactive records storage that meets NARA requirements; the records are maintained for their retention period in accordance with the DOE Records Disposition Schedules.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

2.0 Contents

Procedures	Procedure Content
IP-414-04, Quality Records	• Defines the Quality Assurance requirements and processes associated with QA records at the EMCBC.

3.0 Exhibits/Forms

None

4.0 Related Information

None

5.0 Requirements

10 CFR 830, Subpart A, *Quality Assurance Requirements*
DOE O 414.1D, *Quality Assurance*

EM-QA-001 Rev 1, *EM Quality Assurance Program (QAP)*

6.0 Definitions

See Implementing Procedures.